DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 23, 2015

Vision Quest Industries, Inc.
Mr. Mohammed Ouerghi
Director of QA/RA
1390 Decision Street, Suite A
Vista, CA 92081

Re: K142236
Trade/Device Name: BioniCare Hand System, Model BIO-2000
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: NYN
Dated: February 17, 2015
Received: February 19, 2015

Dear Mr. Ouerghi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142236

Device Name
BioniCare Hand System, Model BIO-2000

Indications for Use *(Describe)*
The BioniCare Hand System, Model BIO-2000, is indicated for use as an adjunctive therapy in reducing the level of pain and stiffness associated with pain from rheumatoid arthritis of the hand.

The BioniCare Hand System, Model BIO-2000, is indicated for use as an adjunctive therapy in osteoarthritis of the hand to reduce the level of pain and stiffness and to improve the function of the hand.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

510(k) Owner:	Vision Quest Industries, Inc. 18011 Mitchell South, Irvine, CA, 92614
Contact:	Mohamed Ouerghi Director of QA/RA Vision Quest Industries, Inc. Phone 760-477-8201 Mobile 760-691-0168 Fax 760-727-5950 mouerghi@vqorthocare.com
Date Summary Prepared:	3/23/2015
Proprietary Name:	BioniCare Hand System, Model BIO-2000
Device Name and Classification:	Transcutaneous Electrical Nerve Stimulator For pain relief, Class II, 21 CFR 882.5890, Product Code NYN
Predicate Devices:	BioniCare® Stimulator, Model BIO-1000, k052625 and k030332
Device Description:	The BioniCare Hand System, Model BIO-2000 is portable, rechargeable, battery-operated, single Channel device that utilizes a voltage regulated output circuit to generate a spike-shaped Monophasic pulse with adjustable amplitude of 0 - 15 volts peak and repeating at a single fixed frequency of 100 ± 5 Hertz. The device consists of electrodes, lead wires and a signal generator (BioniCare® Stimulator).
Statement of Intended Use:	The BioniCare Hand System, Model BIO-2000, is intended for use by patients with rheumatoid and/or osteoarthritis of the hand as: • An adjunctive therapy in reducing the level of pain and stiffness associated with pain from rheumatoid arthritis of the hand. • As an adjunctive therapy in osteoarthritis of the hand to reduce the level of pain and stiffness and to improve the function of the hand.

Clinical Study Results and Summary:

The study was designed as a prospective, multi center, open-label study to evaluate the efficacy and safety of the BioniCare Hand System in the treatment of Osteoarthritis of the hand. Patients were entered from the investigating physicians practice, without advertising, if they were 18 years or older, had osteoarthritis of the hand that was symptomatic for at least 3 months with a pain score of at least 3 out of 10 on a VAS scale despite stable NSAIDs and/or analgesics for at least a month prior to study entry. Eighty two patients were enrolled, 66 females and 16 males, with a mean age of 64 and a range of 45 to 89 years. When both hands were effected the more symptomatic hand was designated the index hand to be treated. The primary outcome measure was osteoarthritis pain in the last 48 hours. Additional efficacy outcomes were pain in the study thumb in the last 48 hours, patient global assessment and the physicians global assessment. Efficacy assessment of function included the validated DASH functional assessment questionnaire and the traditional measures of strength, pinch force and grip strength as measured by a JAMAR Hand Assessment Kit which includes a squeeze (grip) dynamometer and a pinch dynamometer. Efficacy was expressed for each variable as the effect size. Effect sizes are generally recognized to be small if they are from 0.2-0.49, moderate from 0.5 to 0.99 and large if they are 1.0 or greater.
In the intent-to-treat statistical analysis, after 8 weeks of treatment, the effect size for OA pain in the study hand in the past 48 hours was 1.3, for OA pain in the study thumb for the past 48 hours was 0.8, for patient global assessment was 1.2, and for physician global assessment was 1.1. Functional outcome was moderately improved by the DASH Score with an effect size of 0.5. Smaller but still significant effect sizes were seen for the additional functional outcomes of pinch force, effect size 0.4 and grip strength with an effect size of 0.3. A limitation of this trial is that it was an open label study which includes the likelihood of bias caused by placebo effect. This was partially compensated by maintaining patients on stable NSAIDs and/or analgesics for the month prior to and for the entire study. This makes it more difficult to show efficacy as the benefit must be in addition to that of NSAIDs and/or analgesics. For example meta-analytic studies have shown an effect size for acetaminophen of 0.21 (95% confidence interval 0.02-0.41) and an effect size for NSAIDs of 0.32 (0.24-0.39). It should be noted that these effect sizes were in comparison to placebo. However, it should also be noted that all of the trials required discontinuation of previous pharmacotherapy for 3 to 14 days prior to study entry. The majority of trials additionally required a pre-defined flare of symptoms when NSAID treatment was discontinued in the pretreatment washout. This pretreatment washout and flair requirement makes it easier to demonstrate effectiveness by any treatment. This was evidenced by the mete-analysis as when they removed the studies which excluded non-responders to NSAID treatment the effect size for pain decreased to 0.23 (0.15-0.31). Thus, even the effect size for pinch force and grip strength (0.4 and 0.3 respectively) are respectable, particularly since multiple studies have demonstrated that surgery of the hand can improve pain but does not increase strength as measured by pinch force and grip strength.

Open label clinical data was used to support the Substantial Equivalence of the BIO-2000 to the predicate. VQ OrthoCare conducted randomized controlled clinical trials to support

clearance of the BioniCare BIO-1000 for rheumatoid arthritis (RA) of the hand and Osteoarthritis (OA) of the knee. Given that the pathophysiological process of osteoarthritis of the knee is similar to the degenerative process that would occur in the hand, data was leveraged from the randomized controlled clinical trial of the knee. The device was previously cleared for Rheumatoid Arthritis of the hand which is a more destructive process (worst case scenario) when compared to OA of the hand. Hence, the clinical data presented in support of the BioniCare BIO-2000 was found to be adequate to support Substantial Equivalence of this device to the predicate.

Substantial Equivalence

The device is substantially equivalent to the predicate devices because all changes made are categorized as changes to Performance Specifications, Ergonomics of User Interface and/or Firmware as the following tables demonstrate.

BIO-2000/BIO-1000 Equivalency Table

510(k) Number	K052625	K142236
Device Name	BIO-1000	BIO-2000
Manufacturer	BioniCare	VQ OrthoCare
Power Source	One 9V battery	One 3.7V battery
No. of Output Modes	1	1
Channels	2	1
Synchronous	Yes	N/A
Reciprocal	No	N/A
Computerized	No	Yes
Software Provided	N/A	Yes - Embedded Firmware
Constant Current	No	No
Constant Voltage	Yes	Yes
Channel Isolation as per AAMI NS4 3.2.3.2	No	N/A
Line Current Isolation	N/A	N/A
Automatic Overload Trip	No	No
Automatic No-Load Trip	Yes	Yes
Patient Override Control	No	No
Max Leakage Current	N/A	N/A
Indicator Display Unit Functioning Low Battery Other	 Yes Yes LCD panel displays all parameter settings.	 Yes Yes LCD panel displays all parameter settings.
Standards - AAMI NS4	Yes - applicable parts	Yes - applicable parts

Timer Settings	No	No
Automatic Shut Off	N/A	N/A
Frequency	100 Hz.	100 Hz.
Waveform	Monophasic spike shaped pulse	Monophasic spike shaped pulse
Voltage Output	0 -12 Volts	0 -12 Volts (0 - 15V mfr override option)
Voltage Pulse Width (% of peak)	1.8mS @ 10%; 0.64mS @ 50%	1.8mS @ 10%; 0.64mS @ 50%
Current Output Range (500 Ohms)	0 - 24mA peak	0 - 24mA peak (30mA option)
Peak Charge (500 Ohm)	20uC	20uC (25uC optional)
Average Power (500 Ohm)	.092W	.092W (0.115W optional)
Minimum Electrode Size	>30cm^2	>30cm^2
Peak Current Density	< 0.667uC/cm^2	< 0.667uC/cm^2 (< 0.833uC/cm^2 optional)
Below AAMI NS4 Safe current limit (20uC + (0.8)(35t)uC	Yes (limit is 50.8uC)	Yes (limit is 50.8uC)
Less than AAMI safe average power (0.25W/ cm^2)	Yes: 0.003W/ cm^2	Yes: 0.003W/ cm^2 (0.0036W/ cm^2 optional)
Area of stimulation	hand	hand
Weight (with batteries) in grams	136	72
Dimensions (mm)	63.9 X 96.4 X 36.9	54.0 X 90.5 X 14.7
Construction	Molded ABS/PC housing	Molded ABS/PC housing

Summary of Non-Clinical Testing

The device and accessories were tested thoroughly using standard test equipment and methods and in accordance with company SOP's. All testing verified conformance to specifications as provided in 510(k). The device is substantially equivalent to the predicate devices. The following table contains a list of some of the non-clinical testing performed.

Test or Standard	**Name**	**Purpose**
IEC 60601-1:1998 +A1:1991 +A2:1995	Medical electrical equipment – Part 1: General requirements for safety and Essential Performance	Safety and Essential Performance
IEC 60601-1-2:2001	Medical electrical equipment. General requirements for safety. Collateral	Electromagnetic Compatibility

+A1:2004	standard. Electromagnetic compatibility. Requirements and tests.	
IEC 60601-2-10:1987 1.0b +A1:2001	Medical electrical equipment. Part 2: Particular requirements for the safety of nerve and muscle stimulators	Safety and Essential Performance
IEC 60601-1-11:2010	Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	Safety and Essential Performance
P10-04-22R	Design Hardware Verification Report	Bench Verification and Functional Testing for substantial equivalence and or verification of performance enhancement
P10-04-20R	Design Validation Report	Voice of the Customer

Summary

The BioniCare Hand System stimulator generates a waveform with proven benefit that is substantially equivalent to the waveform provided by the predicate devices. This waveform used has been demonstrated in predicated devices to be effective as an adjunctive therapy in Osteoarthritis to reduce the level of pain and stiffness. The BioniCare Hand System delivers this same waveform in an effective manner to the hand.